REMARKS

The final Office Action dated December 29, 2004 has been carefully considered. Upon entry of this amendment, claims 1-6, 8-30 and 60-64 will be pending in this application. Claim 31 has been cancelled without prejudice. Applicants fully reserve the right to prosecute the subject matter of the cancelled claim in one or more related applications. In addition, claim 64 has been added.

Claims 1-6, 8-30 and 60-63 have been amended to correct minor editorial errors and to more clearly point out certain embodiments of the present invention. Specifically, claim 1 has been amended to include the recitation of cancelled claim 31. Support for amended claim1 can be found in the present specification at, *inter alia*, page 3, line 31 to page 4, line 1; page 4, lines 27-33; page 5, lines 20-21; page 6, lines 10-14; and claims 1, 7, 21 and 31 as originally filed. Support for amended claim 60 can be found in the present specification at, *inter alia*, page 3, line 31 to page 4, line 1; page 4, lines 20 and 27-33; page 5, lines 20-21; page 6, lines 10-14; and claims 1, 21 and 31 as originally filed. New claim 64 has been added to recite an implant made by the method of claim 21. Support for new claim 64 can be found in the present specification at, *inter alia*, page 6, lines 10-14; and claim 31 as originally filed. Claim 21 has been rewritten as an independent claim, the dependency of claims 62 and 63 has been amended, and certain minor editorial errors in claims 1-6, 8-30 and 60-63 have been corrected. No new matter has been added.

Withdrawal of the finality of the Office Action dated December 29, 2004, reconsideration of the present application, and entry of the above claim amendments and following remarks are respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 1-5, 8-19 and 21-31 Are Patentable Over International Publication No. WO 93/20859 To Arm *et al.* ("Arm")

Claims 1-5, 8-19 and 21-30 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Arm. Applicants respectfully disagree.

A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and the content of the prior art, the differences between the invention and the prior art, the level of the ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Graham v. Deere, 383 U.S. 1 (1966). The relevant inquiry is

whether the prior art suggests the invention, and whether one of ordinary skill in the art would have had a reasonable expectation that the claimed invention would be successful. In re O'Farrell, 853 F.2d 894, 902-4 (Fed. Cir. 1988); In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. In re Dow Chemical Co., 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). In determining obviousness, "the inquiry is not whether each element existed in prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed." Hartness International Inc. v. Simplimatic Engineering Co., 819 F.2d 1100, 2 U.S.P.Q.2d 1826 (Fed. Cir. 1987).

Amended claim 1 is directed to an implant comprising a varnish-like coating having a thickness of 100 μm or less and made of a biodegradable polymer having a mean molecular weight of 100 kDa or less, wherein the varnish-like coating forms an adhesive bond to the surface of the implant. The implant is made by preparing a dispersion of the biodegradable polymer in an organic solvent; applying the dispersion on the surface of the implant; and evaporating the solvent. Claims 2-5 and 8-19 depend from claim 1 and thus also include these limitations.

As stated in the present specification, a varnish-like coating "means that the coating bonds with the surface of the base material [of an implant] with enough adhesive strength such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect" (*see* present specification, page 4, lines 28-31). It is this adhesive strength that ensures the coating is not degraded during insertion of the implant into the body. For example, as described in the present specification, it is understood that one may properly drive a nail, provided with the varnish-like coating, into the bone without any significant abrasion of the varnish-like coating (*see* present specification, page 4, lines 32-33).

Arm does not disclose or suggest an implant comprising a body having a varnish-like coating that forms an adhesive bond to the surface of the implant as recited in amended claim 1 for the reasons discussed in the Amendments filed on September 29, 2003, May 26, 2004, and September 15, 2004, and the following reasons.

Arm discloses wrapping a pre-prepared biodegradable film around surgical screws, rods, pins, plates and the like (*see* Arm, page 13, lines 6-13). Arm only discloses a film that is used alone or is prefabricated before it is applied to an implant. In particular, Arm discloses a biodegradable film which is constructed before it is subsequently rolled or wrapped around an implant or used alone (*see, e.g.,* Arm, page 4, lines 21-25; page 5, lines

27-34; page 13, lines 1-33; page 15, lines 3-15; page 16, lines 18-30; page 18, lines 3-9 and 27-29; page 19, lines 3-9). For example, Arm discloses that the films are made by "combining the desired amount of PLA/PGA copolymer granules in a suitable solvent (e.g. choloroform or methylene chloride), pouring the resulting solution into a mold, and completely evaporating the solvent. In the alternative, PLA/PGA films may be produced by compression molding, extrusion, or other known methods." (Arm, page 5, lines 28-34). After being made, Arm's film can be stored refrigerated (*see* Arm, page 13, lines 6-8), loaded with a carrier such as albumin (*see* Arm, page 4, lines 6-7; page 11, lines 18-20; page 16, lines 18-23; page 18, line 5), and cut to a specific size (*see* Arm, page 15, lines 12-13; Table 1 on page 16) before it is rolled around or applied directly to an implant. (*see* Arm, Examples 1-5). In fact, all of the Examples in Arm disclose prefabricating the film (*see* Arm, Examples 1-5). For instance, Examples 1-4 disclose rolling the film around an implant and Example 5 discloses constructing and applying a film to an implant. (*see* Arm, Example 1 at page 15, lines 13-15; Example 2 at page 16, lines 23-25; Example 3 at page 18, lines 7-9; Example 4 at page 18, lines 28-29; Example 5 at page 19, lines 7-9).

While Arm's film is prefabricated as discussed above, the presently-claimed implant having a varnish-like coating is made by mixing a biodegradable polymer with an organic solvent to form a dispersion, applying the dispersion on a surface of the implant, and then evaporating the organic solvent. Not only does Arm fail to teach or suggest applying a dispersion directly to an implant and then evaporating the inorganic solvent on the implant itself, but Arm also teaches away from the claimed invention by disclosing a prefabricated film.

According to MPEP § 2113, "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where . . . the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." The presently-claimed implant is made by preparing a dispersion of the biodegradable polymer in an organic solvent; applying the dispersion on the surface of the implant; and evaporating the solvent. Such process results in an implant having a varnish-like coating that forms an adhesive bond to the surface of the implant "such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect" (*see* present specification, page 4, lines 28-31). However, as stated in the present specification, Arm "describes the fabrication of a thin foil or film. . . The intent is to wrap a foil of that type, for instance, around fracture-fixation devices prior to their implantation. . . .

In practice, however, this method is unsuitable since a nail wrapped with a foil of that type cannot be inserted in the medulla in a way that the foil, which only loosely envelops the nail, actually reaches the point of its intended healing action." (*see* present specification, page 1, lines 25-32). Thus, the resultant implant of Arm would not be the same as that presently claimed in claim 1.

Moreover, one of ordinary skill in the art would not find a suggestion or motivation in the disclosure of Arm to apply or modify the teachings of Arm to arrive at the claimed invention, particularly where Arm does not even disclose or suggest a varnish-like coating and Arm's film is prepared in a different manner than the varnish-like coating used in the claimed invention.

Therefore, amended claim 1 and claims 2-5 and 8-19, which are dependent on amended claim 1, and are believed to be patentable over Arm.

Furthermore, amended claims 14, 15 and 19 are patentable over Arm for the following additional reasons. Arm discloses that the growth factor "will typically be provided in an amount between 0.0375 and 1.25[1] μg per mg of copolymer" (*see* Arm, page 12, lines 19-20), which is equivalent to about 0.0375 and 0.125% by weight, respectively. However, as recited in amended claims 14 and 15, the amount of growth factor employed in the total weight of the coating of the instantly claimed implant is 0.5% to 8% and 1 to 5% by weight, respectively. The percentages disclosed in Arm clearly fall outside the percentages recited in amended claims 14 and 15. Therefore, Arm does not disclose or suggest the percentage of growth factor by total weight of the coating, as claimed in amended claims 14 and 15. Arm also fails to teach or suggest the recited percentage of IGF-I and TGF-β that is to be used in the coating of the implant of amended claim 19. As such, amended claims 14, 15 and 19 are believed to be patentable over Arm.

Arm also does not disclose or suggest the method of claim 21. Amended claim 21 is directed to a method of making an implant comprising a varnish-like coating that forms an adhesive bond to the surface of the implant wherein the method comprises the steps of (a) preparing a dispersion of the biodegradable polymer in an organic solvent; (b) applying the dispersion on the surface of the implant; and (c) evaporating the organic solvent. Claims 22-30 depend from claim 21 and, thus, also include these limitations. As previously described, Arm does not disclose or suggest applying the dispersion on a surface of the implant to be coated and then allowing the solvent to evaporate, as required by amended claim 21. Instead,

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[1] Applicants submit that the Examiner has incorrectly indicated on page 4, line 10 of the Office Action that Arm teaches amounts of 0.0375 and 1.5 micrograms per mg of copolymer.

Arm's film is prefabricated prior to it being affixed to an implant and, therefore, the solvent is not evaporated after it is applied to the implant, as discussed above. As such, amended claim 21, as well as dependent claims 22-30, are believed to be patentable over Arm.

Amended claims 23 and 24 are patentable over Arm for additional reasons. Amended claim 23 further requires that the evaporation of the solvent occurs in a gaseous atmosphere substantially saturated with solvent vapor. Arm does not disclose or suggest evaporating the solvent in a gaseous atmosphere substantially saturated with solvent vapor. Arm, by contrast, discloses allowing the solvent to evaporate completely in a slow air flow hood (*see* Arm, page 15, lines 8-9). Amended claim 24 recites that the polymer/solvent dispersion is applied to the implant and evaporated for at least two times, *i.e.*, the dispersion is applied and evaporated for a first time, then the dispersion is applied and evaporated for a second time, and so forth. Arm does not teach or suggest applying a polymer dispersion to an implant and evaporating the solvent after the dispersion has been applied to the implant, much less teach or suggest applying a polymer dispersion to an implant and evaporating the solvent more than one time. As such, amended claims 23 and 24 are believed to be patentable over Arm.

For the foregoing reasons, amended claims 1-5, 8-19 and 21-30 are believed to be patentable over Arm and, therefore, Applicants respectfully request that the rejection based on this reference be withdrawn. For the reasons discussed above, new claim 64 is also believed to be patentable over Arm.

B. Claims 60-63 Are Patentable Over Arm In View Of U.S. Patent No. 6,530,951 B1 To Bates *et al.* ("Bates")

Claims 60-63 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Arm in view of Bates. This rejection is respectfully traversed.

Claim 60 is directed to an implant for compensating for pathological changes in the spinal column or locomotor system wherein the implant comprises a body having a varnish-like coating and a base material which is not biodegradable. The varnish-like coating forms an adhesive bond to the surface of the implant. The implant is made by preparing a dispersion of a biodegradable polymer in an organic solvent; applying the dispersion on the surface of the implant, and evaporating the organic solvent. Claims 61-63 depend from claim 60 and, thus, also include those limitations.

As discussed above, Arm does not teach or suggest and, in fact, teaches away from a varnish-like coating. As noted by the Examiner, there is also no teaching or suggestion in

Arm of a base material that is not biodegradable. Bates does not cure the deficiencies of Arm.

Like Arm, Bates does not teach or suggest a varnish-like coating. Moreover, Bates does not even disclose or suggest "an implant for compensating for pathological changes in the spinal column or locomotor system" as recited in amended claim 60. Instead, Bates discloses a silver implantable medical device adapted for introduction into the vascular system, esophagus, trachea, colon, biliary tract, or urinary tract (*see* Bates, Abstract; col. 7, lines 30-34). Bates does not teach or suggest a device that can be applied to a fractured bone, much less teach or suggest bone-repairing devices such as screws, pins, plates, rods, artificial joint component, or bone filing material. Thus, Bates does not disclose or suggest the presently claimed invention.

Moreover, Applicants submit that one of ordinary skill in the art would not find a suggestion or motivation in either Arm or Bates to modify or combine the teachings of these references to arrive at the claimed invention as recited in claim 60, particularly where Arm discloses biodegradable films and devices that are useful for repairing bone fracture (*see* Arm, page 4, lines 19-25) and Bates discloses vascular stents and other implantable medical devices that are useful for minimizing the proliferation of fibroblasts and reducing the incidents of restenosis in stented vessels (*see* Bates, col. 3, lines 48-52).

Even assuming, *arguendo*, that the teachings of Arm and Bates can be modified or combined, which they cannot, Applicants submit that there is no reasonable expectation of success offered by Arm in view of Bates to formulate the claimed implant. As discussed above, Arm relates to bone fracture treatment and Bates relates to vascular treatment. Contrary to the Examiner's allegation, Arm and Bates are not used for the same field of endeavor nor to treat the same problems (*see* Office Action, page 9, lines 13-15). Since vascular diseases and bone repairs are significantly different conditions, one skilled in the art would not expect that the treatment for one condition could successfully be used to treat the other condition. Therefore, based on the teachings of the two references, one skilled in the art would have no reasonable expectation of arriving at the claimed invention.

In addition, Applicants respectfully submit that hindsight reconstruction has been used to pick and choose among isolated disclosures in the cited references to reconstruct the claimed invention. Such hindsight reconstruction, however, is improper. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1560 (Fed. Cir. 1988). Hindsight should be avoided in applying the nonobviousness requirement. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1 USPQ2d 1593 (Fed. Cir. 1987) cert. denied 481 U.S. 1052 (1987). While Arm fails

to teach a varnish-like coating and a base material that is not biodegradable, Bates fails to teach or suggest a varnish-like coating that is biodegradable. Without the benefit of hindsight, there is no suggestion in the references themselves to modify and/or combine the teachings to obtain the present invention.

In view of the foregoing, it is believed that claims 60-63 are patentable over Arm and Bates, whether taken alone or in combination. Thus, Applicants respectfully request that the Examiner withdraw this rejection and allow claims 60-63.

C. Claims 1, 2, 4, 5, 8-10 and 20 Are Patentable Over U.S. Patent No. 4,610,692 to Eitenmuller *et al.* ("Eitenmuller")

Claims 1, 2, 4, 5, 8-10 and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Eitenmuller. This rejection is respectfully traversed.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that Eitenmuller does not teach or suggest each and every claim limitation. Specifically, Eitenmuller does not teach or suggest an implant having a varnish-like coating that forms an adhesive bond to the surface of the implant as presently claimed.

As stated above, "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where . . . the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." MPEP § 2113. The presently-claimed implant is made by a process that results in an implant having a varnish-like coating that forms an adhesive bond to the surface of the implant "such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect" (*see* present specification, page 4, lines 28-31). Eitenmuller does not disclose or suggest coating an implant by preparing a dispersion of the biodegradable polymer in an organic solvent; applying the dispersion on the surface of the implant; and evaporating the organic solvent. Eitenmuller does not even disclose or suggest how the implant is coated. Accordingly, it is respectfully submitted that Eitenmuller does not disclose or suggest the implant recited in claim 1, as amended herein.

Moreover, the Examiner admits that Eitenmuller fails to teach biodegradable polymer having a mean molecular weight of 100 kDa or less (*see* Office Action, page 8, lines 8-9). However, the Examiner contends that absent a showing of criticality, "generally, differences

in molecular weights, will not support the patentability of subject matter encompassed by the prior art" (*see* Office Action, page 8, lines 9-12). The Examiner further contends that "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (*see* Office Action, page 8, lines 12-14).

Eitenmuller is completely silent about the molecular weight of the polymers that can be used in the coating. Contrary to the Examiner's allegation, Eitenmuller does not teach the general conditions of amended claim 1, *i.e.*, having a varnish-like coating of biodegradable polymer that has a specific mean molecular weight such as 100 kDa or less. Eitenmuller does not teach or suggest polymers having any particular molecular weight, much less teach or suggest polymers having a mean molecular weight of 100 kDa or less. At most, Eitenmuller discloses polymethacrylate (*see* Eitenmuller, Examples 1 and 3), polydextran (*see* Eitenmuller, Example 2), and polylactide (*see* Eitenmuller, Example 4) for use in the polymeric coating. Since polymethacrylate, polyactide, and polydextran are polymers that can be of any size/length, one skilled in the art would understand that the polymers disclosed in Eitenmuller can be of any molecular weight. It is not a matter of routine experimentation to arrive at the particular molecular weight as recited in amended claim 1 nor optimization of ranges as the Examiner alleges. Eitenmuller also does not teach or suggest polymers having a particular range of molecular weight that overlap with the range recited in amended claim 1 or is "close enough that one skilled in the art would have expected them to have the same properties" (*see* MPEP § 2144.05(I). Thus, it is respectfully submitted that one skilled in the art would not find any motivation or suggestion in Eitenmuller to use polymers having the molecular weight recited in amended claim 1 to obtain the presently claimed invention.

Accordingly, Applicants submit that Eitenmuller fails to teach or suggest all the claim limitations of amended claim 1 and amended claims 2, 4, 5, 8-10 and 20, which are dependent on amended claim 1.

For the foregoing reasons, amended claims 1, 2, 4, 5, 8-10 and 20 are believed to be patentable over Eitenmuller and, therefore, Applicants respectfully request that the rejection based on this reference be withdrawn and that these claims be allowed.

D. Claims 1-6, 8-12 and 20 Are Patentable Over U.S. Patent No. 5,670,161 to Healy *et al.* ("Healy")

Claims 1-6, 8-12 and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Healy. This rejection is respectfully traversed.

Healy relates to stents for use within a body lumen to provide support for keeping the lumen open (*see* Healy, column 4, lines 19-27). Healy discloses a biodegradable stent made from a copolymer of L-lactide and ε-caprolactone (*see* Healy, col. 3, lines 34-38). Healy does not teach or suggest implants useful for compensating for pathological changes in the spinal column or locomotor system as recited in amended claim 1. Nor does Healy teach or suggest a varnish-like coating that forms an adhesive bond to the surface of the implant. Healy also fails to teach or suggest polymers having particular molecular weight, in particular, a mean molecular weight of 100 kDa or less.

In fact, one skilled in the art would not find any suggestion or motivation in the teachings of Healy to arrive at the claimed invention, particularly where Healy is not even directed to implants for compensating for pathological changes in the spinal column or locomotor system. Moreover, one skilled in the art would not expect the implantable vascular device of Healy to be usable for compensating for pathological changes in the spinal column or a locomotor system. Therefore, one skilled in the art of spinal column or locomotor system repair would also have no motivation to modify the teaching of Healy to obtain the present invention.

Thus, it is respectfully submitted that Healy does not disclose or suggest the presently claimed invention. As such, amended claim 1, as well as dependent claims 2, 4, 5, 8-10 and 20, are believed to be patentable over Healy. Therefore, Applicants respectfully request that the rejection based on this reference be withdrawn and that claims 1-6, 8-12 and 20 be allowed.

CONCLUSION

In light of the above remarks, it is submitted that all outstanding rejections have been overcome. Attorneys for Applicants respectfully submit that the claims fully meet all statutory requirements for patentability. Withdrawal of the rejections and allowance of amended claims 1-6, 8-30 and 60-63 and new claim 64 are respectfully requested. Should the Examiner not agree with Applicants' position, then a telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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